Form Approved
OMB No. 0920-0109
Exp. Date xx/xx/20xx

NIOSH RESPIRATOR APPROVAL PROGRAM QUESTIONNAIRE FOR POTENTIAL APPLICANTS

Section A. Company Information

What is the (registered) name of the company intending to apply for NIOSH approval?

What is the company's US Tax ID or Employer Identification Number (EIN)? Please provide the 9-digit number and the company name associated with it, to facilitate payment processing. Please answer "N/A" if you do not have a US Tax ID or EIN.

Please provide the name, title/role, phone number, email address, and physical work address of **a primary contact** for the company. The primary contact must have the authority to make business and technical decisions on behalf of the company. This individual cannot be a consultant, attorney, and/or distributor and does not need to be an officer in the company. **When an application is offered, NIOSH expects to interact with the primary contact, as needed**.

Please provide the name, title/role, phone number, email address, and physical work address of **at least one alternative contact** for the company. NIOSH will not respond to contacts that are not formally identified.

Please provide a link to the website of the company seeking for NIOSH approval.

Please indicate at which of your locations the following activities occur (provide the complete physical address). If an activity is completed at your identified headquarters (HQ) or manufacturing facilities (MANU) location, please indicate that in the table. You do not need to provide the same address in multiple cells of the table.

Activity	Primary Location	Additional Location(s)
Headquarters		
Manufacturing		
Warehousing		
Design and Development		
Control of Documents and Data		
Purchasing		
Product Identification and Traceability		

Control of Production Processes		
Inspection and Test		
Control of Equipment		
Inspection and Test Status and Control of Nonconforming Product		
Corrective Actions		
Inventory and Handling Controls		
Quality Records		

Section B. Quality System

Have you implemented a quality control system that includes the requirements in 42 CFR 84, Subpart E and completely addresses the information provided in Conformity Assessment Notice, NIOSH CA 2019-1019?

Does your quality control system include incoming and final inspections, sampled based on variables or attributes, to ensure that critical respirator performance requirements are met 84.41(a-h)?

Section C. Product Details

Has your company produced a respirator (*a device designed to provide the wearer with respiratory protection against inhalation of a hazardous atmosphere in an occupational setting*) using the documented quality assurance processes and procedures? This is a critical aspect of NIOSH approval that must be completed before you can apply, see 42 CFR 84.

For which type of respirator will you be seeking NIOSH approval? What protections will it provide? (The protections are described in the NIOSH Standard Application Procedures).

Has your current / final respirator design been evaluated against the NIOSH Standard Test Procedures (STPs) to verify the performance of the design? If yes, **please list the NIOSH STP numbers** that you are using. Do not provide references to third party laboratory procedures.

Section D. Additional Information

With the completed questionnaire you will need to include 1) a photo of the facility showing the company name on the building, as it appears, please DO NOT send altered images, 2) a photo of the quality assurance area, 3) a photo of the production line 4) a photo of the first respirator that will be submitted for approval. **Please include these as individual image file attachments (jpeg).**

Section E. Signature and Attestation

By my signature and submission of these responses, I attest that:

- I have answered the questions in this form truthfully.
- I acknowledge that I understand that the manufacturers code for which I am hereby applying does not indicate or imply NIOSH approval of any respirator.

Signature:

Print name:

Title / Role:

Date: